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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/518,386 | 05/03/2005 | Katarzyna Jureczek | 1034433-000009 (078556-01) | 6605 |
| 23524 7590 06/27/2008 FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497 | | | | |
| EXAMINER | | | | |
| YOUNG, MICAH PAUL | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1618 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,386

Applicant(s)

JURECZEK, KATARZYNA

Examiner

MICAH-PAUL YOUNG

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date 5/3/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/03/05 was filed after the mailing date of the Specification on 12/29/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damien et al (*Review Article XP009004369* hereafter '369) in view Tobin et al (USPN 6,077,534 hereafter '534) and Conte et al (USPN 6,294,200 hereafter '200). The claims are drawn to a sustained release tablet comprising a low dose of indapamide and a carrier composition.

The '369 patent discloses a sustained release tablet comprising a low dose formulation of indapamide (abstract). The sustained release tablet comprises ~60% lactose monohydrate, ~4% povidone, ~31% hypromellose and ~.6% lubricants such as colloidal silica and magnesium stearate (Table 1). The tablet can be made either by direct compression or by wet granulation where the components are mixed and wetted using a common wet granulation method and then compressed into tablets (paragraph 1.1).

The reference discloses a sustained release tablet comprising povidone and hypromellose, yet is silent to the inclusion of copovidone or the specific viscosity of the hypromellose. The substitution of the povidone for a copovidone would be obvious to one of ordinary skill in the art in order to improve the binding properties of the formulation. This can be seen in the '534 patent.

The '534 patent discloses a sustained release formulation (abstract). Copovidone is used as a binding agent in a concentration of 1-15 parts (col. 8, lin. 10-20). The formulation can further include diuretics along with other well known pharmaceuticals (col. 10, lin. 62-col. 11, lin. 8). It would have been obvious to include the copovidone of the '534 patent in order to improved the binding properties, thereby extending the sustained releasing nature of the tablet.

The '200 patent discloses a sustained release tablet comprising indapamide (col. 8, lin. 23). The tablet comprises lactose, povidone, and hypromellose (col. 4, lin. 55-65; col. 5, lin. 30-41; col. 6, lin. 40-48, example). The tablet comprises hypromellose with a viscosity from 4,000-150,000 cP (claims). It would have been obvious to include the polymers of the reference since the formulation are similar and the hypromellose would improve the release rates of the resultant tablet.

Regarding the specific concentrations of the excipients, it is the position of the Examiner that these limitations are merely the result of routine experimentation by those of ordinary skill in the art. The prior art provides a sustained release tablet comprising a low dose of indapamide, similar concentrations of lactose monohydrate, copovidone, hypromellose and lubricants, all mixed and compressed into concentrations a wet granulation technique. The prior art meets the general conditions of the instant claims. Applicant is reminded that Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to combine the prior art in order to improve the binding and sustained release properties of the tablet. It would have been obvious to substitute copovidone for the povidone of the '369 reference in order to increase the binding of the formulation and thus prolong the release of the drug compound. It would have been obvious to include hypromellose of the viscosity of the '200 patent in order to better control the release of the drug compounds. One of ordinary skill in the art would have been motivated to make these

combinations with an expected result of a sustained release tablet useful in treating various disorders over an extended period of time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

